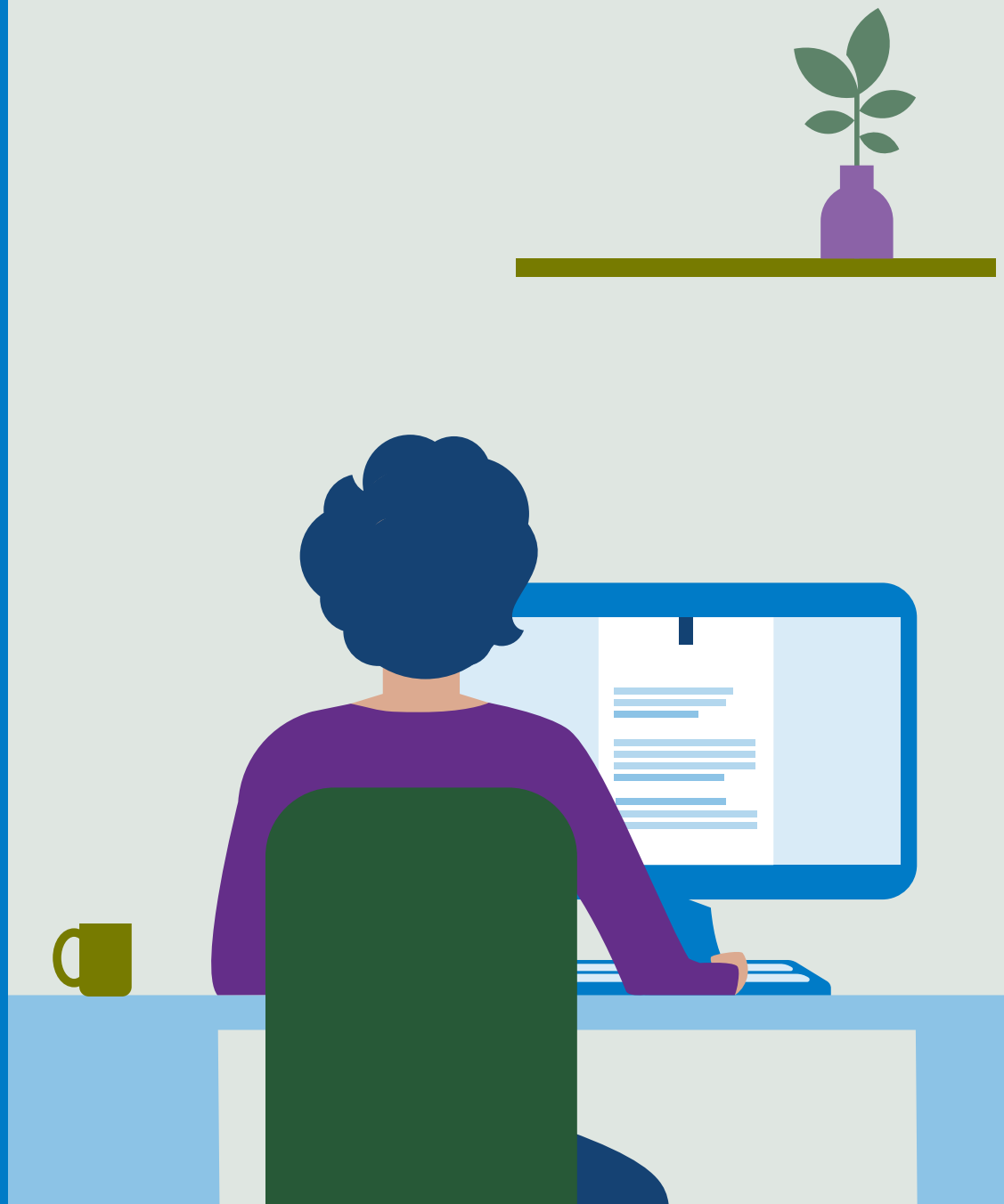
Central Authority for Scientific Procedures on Animals

Defining a project

Guideline issued by the Central Authority for Scientific Procedures on Animals



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Introduction

The Central Authority for Scientific Procedures on Animals (CCD) assesses applications for a project licence on various criteria. First of all, project applications must fall within the scope of a project. This guide addresses the assessment criteria used by CCD to determine whether an application meets its definition of a 'project'. It is intended to support researchers, Animal Welfare Bodies (AWBs) and Animal Ethics Committees (DECs) in understanding the guidelines for defining an application for a project licence.

Disclaimer: *This document may contain translations of Dutch legal texts. These are unofficial and for informational purposes only. In case of discrepancies, the original Dutch legislation prevails.*

Legal framework

Article 1(1b) of the Dutch 'Animal Experiments Act' (Wet op de dierproeven) defines a project as follows: "een werkprogramma met een welomschreven doel dat één of meer dierproeven omvat", meaning a work programme with a clearly defined goal that includes one or more animal procedures. This means that the project's experimental design and objective must be clearly defined.

Under Article 10a(7) of the Act, the comprehensiveness of the assessment should be proportionate to the type of project in question. The assessment should also be comprehensive enough to determine whether the project satisfies the criteria set out in Article 10a2. The nature of the assessment (and therefore the comprehensiveness of the 'work programme') therefore depends on the project.

When describing their experiments in their application, the applicants choose a certain level of aggregation; applicants themselves are best placed to describe the nature and potential benefits of their research. This choice indicates the main objectives and any sub-objectives within the project.

Researchers, AWBs and DECs can use this guide to determine whether the definition of a project is correctly defined in a project application based on the chosen level of aggregation. Of course, it is important for all parties involved to use the same frame of reference. The following factors were considered when drafting this guide.

1. The ethical review framework developed by CCD: "What aspects must always be considered when assessing project licence applications?". The guide to the ethical review framework for the use of laboratory animals (Ethisch toetsingskader voor proefdiergebruik) is available in Dutch on the CCD website;
2. CCD's past experience with assessing project licence applications.

More information about submitting an application is available on the CCD website, please see the page *Applying for a project licence*.

A number of examples have been developed to illustrate how the CCD applies this guide in practice.

Assessment criteria

1. Has the objective been described clearly? Is its scope suitable for the chosen category/categories of study objectives? Is the objective feasible within the duration of the project and aligned with the capabilities and resources of the research group?

Please note: Demonstrable experiences and results from past research are highly relevant.

2. Is there a logical relationship between the primary objective(s) and any sub-objectives? Do the various activities form a coherent whole, given the specific primary objective?

Please note: In some cases, there may be so much uncertainty regarding the achievability of the specified objectives and sub-objectives that these objectives cannot be assessed. This can happen when there are many different go/ no go decision moments regarding whether or not to conduct experiments or which type of experiment should be conducted.

Regulatory research and routine production

Article 10a1(5) of the Act states that a project licence is required for all regulatory, diagnostic or routine production related research. In some cases, the information required to describe the points mentioned earlier in sufficient detail may not yet be available. This problem may arise in project licence applications submitted by contract research organisations (CROs) or knowledge institutions, as in many cases insufficient information is available about the substances or substance categories to be tested. When this information is not available in advance, a long-term licence may be approved and issued on condition that the applicants submit annual reports, filling in the missing information once it becomes available. These reports must be submitted every year before 1 April. An explanation of this CRO reporting ('Toelichting terugkoppeling CRO') is available in Dutch on the CCD website.

Practical examples

It is entirely coincidental that the below diagrams all contain a single primary objective and three sub-objectives. In practice, there may be more or fewer. The detailed description of the sub-objectives may be provided in one or more appendices description animal procedures. Below the diagrams, the essential components for conducting a harm–benefit analysis are discussed. These components determine whether an application meets its definition of a 'project'.

Scenario 1: fundamental and translational research

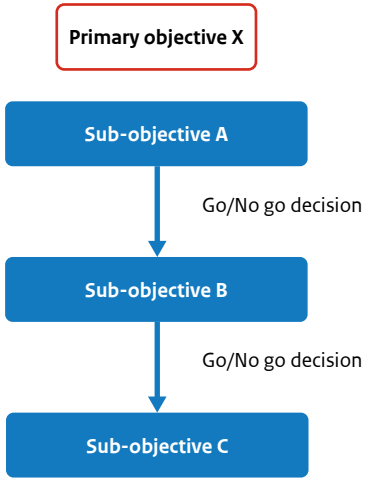

Figure 1: Example illustrating the course of fundamental and translational research

Correct application of the definition of a project

Example: Sub-objectives A and B relate to fundamental research, while sub-objective C relates to translational research.

- The primary objective (hypothesis) is clearly defined;
- The relationship between the primary objective and sub-objectives is clearly defined;
- The various sub-objectives are fully defined;
- The Go/No go or decision points for the various sub-objectives are clearly defined and well-reasoned;
- The sub-objectives are independent of each other, in terms of time and results, and form a single entity;
- Achieving the sub-objectives ultimately leads to achieving primary objective X;
- It is not possible to assess the individual objectives, because they are interdependent.

Conclusion: This is an example of a correct interpretation of the definition of a project. All necessary information is available. The various sub-objectives described in the project application, when taken together, form a clear, coherent whole. It is possible to conduct a comprehensive harm-benefit analysis.

Incorrect application of the definition of a project

Example: Sub-objectives A and B relate to fundamental research, while sub-objective C relates to translational research.

- The primary objective (hypothesis) is clearly defined;
- Only sub-objective A is fully defined;
- The detailed implementation of sub-objectives B and C depends on the results of sub-objective A;
- The uncertainty regarding the number of animals and their expected level of discomfort in sub-objectives B and C is still too great to allow for a complete ethical review.

Conclusion: This is an example of an incorrect interpretation of the definition of a project. Although it is possible to conduct a comprehensive harm-benefit analysis for sub-objective A, this is not yet possible for sub-objectives B and C. In this case a licence is only granted and issued for sub-objective A. Because the detailed implementation of sub-objectives B and C depends on the results from A, some of the elements necessary for a harm-benefit analysis are not yet clear or well-reasoned. The CCD can choose to reject the application or, for example, grant and issue a project licence under certain conditions; in the latter case, an interim report must be submitted, describing the results of sub-objective A and giving a more detailed description of sub-objectives B and C. Following the interim report and the provision of the previously missing details, the CCD may proceed with the assessment of sub-objectives B and C.

Scenario 2: fundamental research

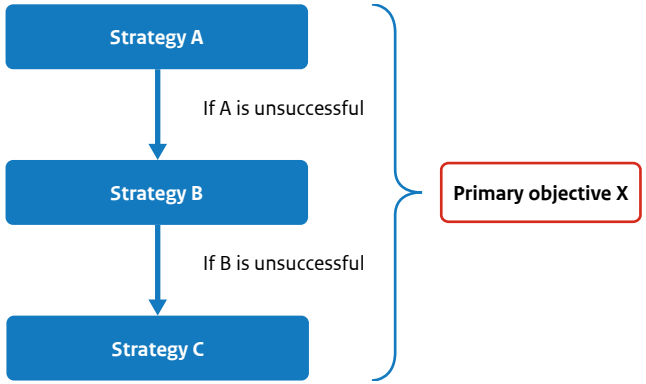

Figure 2: Example illustrating the course of fundamental research

Regarding fundamental research:

- The primary objective (hypothesis) is clearly defined;
- The various experimental strategies (A, B, C) to achieve the primary objective are fully descripted, including the decision points. A harm-benefit analysis can be conducted for all animals;
- If the primary objective can be fully achieved using one of each of these three alternative strategies, the strategies must be set out in order of likelihood of success: Strategy B will only go ahead if Strategy A is unsuccessful, and Strategy C serves as back-up for Strategy B. The assessment can be based on this worst-case scenario;
- Although each strategy is different, each of the specified strategies could achieve primary objective X;
- The three different strategies can only be implemented simultaneously if primary objective X can only be achieved by comparing the results of all three strategies.

Conclusion: This is an example of a correct interpretation of the definition of a project. All necessary information is available. The various sub-objectives described in the project application, when taken together, form a clear, coherent whole. Decision points are specified, and it is clear when and how the decisions will be made and what their potential consequences are for all animals. It is possible to conduct a comprehensive harm-benefit analysis.

Scenario 3: fundamental and/or translational research

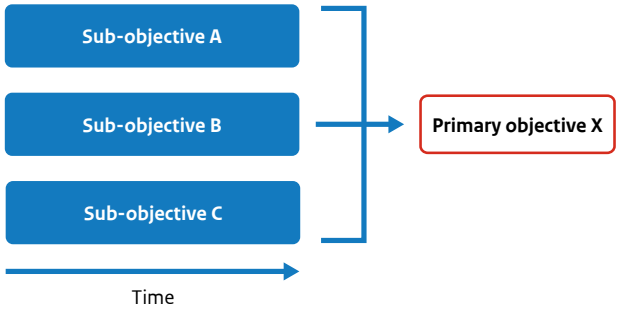

Figure 3: Example illustrating the course of fundamental and/or translational research

Correct application of the definition of a project

Regarding fundamental or translational research or a combination of the two:

- The primary objective is clearly described: the sub-objectives are not mutually related in any way and are not time-dependent on each other;
- The animal procedures for the various sub-objectives can be carried out independently from and simultaneously with each other, and each sub-objective contributes to the primary objective;
- The strategy for each sub-objective is clear, including the project's go/no go decision points, how decisions will be made regarding the progress of the project, and which procedures will be carried out on the animals for each sub-objective. In this case, the sub-objectives cannot be treated as separate projects;
- It is likely that the objective will be achieved within the specified duration of the project.

Conclusion: Based on this description, it is possible to assess the combined contribution of each individual research line to the primary objective. Therefore, this is a correct interpretation of the definition of a project. Since it is clear how each sub-objective contributes to achieving the primary objective, a comprehensive harm–benefit analysis can be carried out.

Incorrect application of the definition of a project

Regarding fundamental or translational research or a combination of the two:

- The primary objective is broadly defined, for example in terms of the programme, department or research group;
- Each sub-objective forms a separate research question and could be carried out as its own independent project;
- It is not clear whether the objective will be achieved within the specified duration of the project;
- There is no clear coherence between the sub-objectives, apart from the fact that they each contribute to knowledge about, for instance, the same pathology.

Conclusion: Based on this description, it is not possible to assess the combined contribution of each individual research line to the primary objective. Therefore, this is an incorrect interpretation of the definition of a project. The cohesion is not sufficiently clear; as a result, the course of this project cannot be tracked accurately and the project's achievability cannot be assessed. This means it is not possible to conduct a comprehensive harm-benefit analysis.

Scenario 4: teaching and training

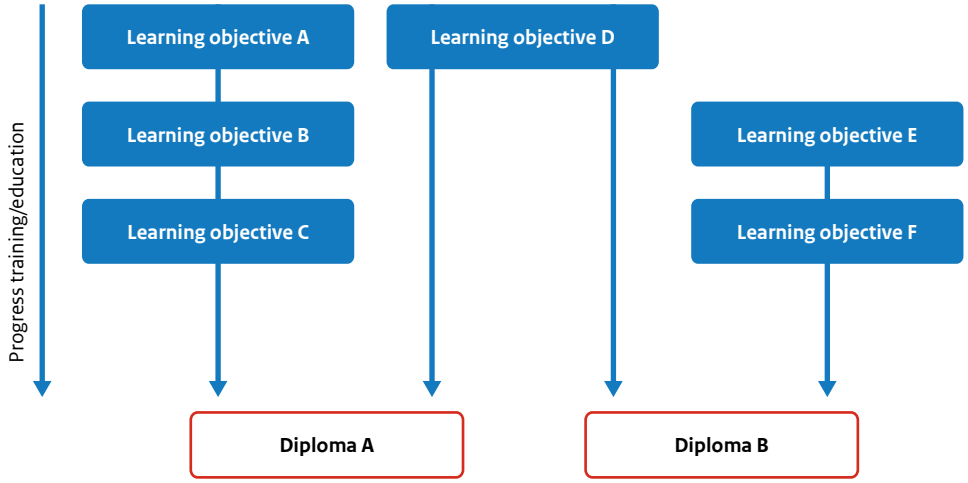

Figure 4: Example illustrating the course of teaching and training projects

Regarding teaching and training projects:

- The primary objective (which may comprise learning objectives from multiple different training programmes or curricula) is clearly defined;
- The various programme elements can be supervised by the researcher responsible;
- Students' level and educational background are made clear before they start the course;
- The need for them to take the course is clear from the learning objectives and/or curriculum, which indicate that no alternative methods can be used;
- Rest periods are clearly defined for teaching animals that are used more than once.

Conclusion: The combination of educational elements leading to the achievement of primary objective X is logically and transparently structured. The discomfort experienced by all animals, as well as the rest periods for animals used in education, is clearly described. The students' level is also specified. This makes it possible to conduct a comprehensive harm-benefit analysis.

This is a publication of the Central Authority for Scientific Procedures on Animals (CCD).

The CCD is the sole competent authority in the Netherlands authorised to grant and issue project licences for conducting animal procedures.

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